**Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])**

## NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

*For official use*

| | |
|---|---|
| Date of receipt : | Competent authority registration number :<br>Ethics committee registration number: |

***To be filled in by the applicant***

**A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE: Denmark**

**B TRIAL IDENTIFICATION**

**B.1 EudraCT number :** 2020-001395-15
**B.2 Sponsor's protocol code number:** protocol version 2.1, 12.05.2020
**B.3 Full title of the trial :** Low-dose hydrocortisone in patients with COVID-19 and severe hypoxia – the COVID STEROID trial

**C APPLICANT IDENTIFICATION** (please tick the appropriate box)

| | | |
|---|---|---|
| **C.1** | **DECLARATION FOR THE COMPETENT AUTHORITY** | ☐ |
| C.1.1 | Sponsor | ☐ |
| C.1.2 | Legal representative of the sponsor | ☐ |
| C.1.3 | Person or organisation authorised by the sponsor to make the application. | ☐ |
| C.1.4 | **Complete below**: | |
| C.1.4.1 | Organisation : | |
| C.1.4.2 | Name of person to contact : Anders Perner | |
| C.1.4.3 | Address : Intensiv Terapiklinik 4131, Rigshospitalet, 2100 København Ø | |
| C.1.4.4 | Telephone number: +45 35458333 | |
| C.1.4.5 | Fax number: - | |
| C.1.4.6 | E-mail: anders.perner@regionh.dk | |

| | | |
|---|---|---|
| **C.2** | **DECLARATION FOR THE ETHICS COMMITTEE** | ☐ |
| C.2.1 | Sponsor | ☐ |
| C.2.2 | Legal representative of the sponsor | ☐ |
| C.2.3 | Person or organisation authorised by the sponsor to make the application. | ☐ |
| C.2.4 | Investigator in charge of the application if applicable[2]: | |
| | • Co-ordinating investigator (for multicentre trial): | ☐ |
| | • Principal investigator (for single centre trial): | ☐ |
| C.2.5 | **Complete below** : | |
| C.2.5.1 | Organisation: | |
| C.2.5.2 | Name : | |
| C.2.5.3 | Address : | |
| C.2.5.4 | Telephone number : | |
| C.2.5.5 | Fax number : | |
| C.2.5.6 | E-mail : | |

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.
2 According to national legislation.

## D END OF TRIAL

| **D.1 Date of the end of the trial in this Member State** ?[3] | yes ☐ no ☐ |
|---|---|
| D.1.1. (YYYY/MM/DD): 12.06.2021 | |

| **D.2** | **Date of the end of the complete trial in all countries concerned by the trial**?[3] | yes ☐ no ☐ |
|---|---|---|
| D.2.1 | (YYYY/MM/DD): 12.06.2021 | |

| **D.3** | **Is it an early termination?**[4] | yes ☒ no ☐ |
|---|---|---|
| D.3.1 | If yes, give date (YYYY/MM/DD): Inclusion was paused on 17.06.2020, and inclusion was terminated on 03.09.2020. Last-patient last-visit is on 12.06.2021. | |
| D.3.2 | Briefly describe in an annex (free text): | |
| D.3.2.1 | The justification for early termination of the trial;<br>Inclusion was paused due to the preliminary results from the RECOVERY trial demonstrating benefit of systemic corticosteroids on short-term mortality. Inclusion was terminated due to an update in the WHO guidelines recommending systemic corticosteroids for all patients with severe or critical COVID-19. | |
| D.3.2.2 | Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;<br>Two patients who were unblinded and both given systemic corticosteroids to complete a course of 10 days. | |
| D.3.2.3 | The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product:<br>We are unable to provide any precise estimates on the benefits and harms of hydrocortisone versus placebo for any outcomes as only 30/1000 patients (3% of the planned sample size) were enrolled in the trial. | |

## E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

**E.1** I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[5]

| **E.2** | **APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1) | ☐ |
|---|---|---|
| E.2.1 | Date : 19/8/21 | |
| E.2.2 | Signature : | |
| E.2.3 | Print name: Anders Perner | |

| **E.3** | **APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:** | ☐ |
|---|---|---|
| E.3.1 | Date : | |
| E.3.2 | Signature : | |
| E.3.3 | Print name: | |

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[3] In case of a multi-country trial, if the national and global end of trial dates are different in a given Member State, the sponsor shall submit this form two times :

1) At the end of the trial in the individual Member State, section D1.1. shall be completed and submitted to the respective National Competent Authority.

2) At the global end of the trial, the sponsor shall complete section D.2.1. with the global trial end date and the completed form shall be submitted to all participating Member States in order to allow the sponsor to prepare the trial result summary within the 12-months (or 6-months in case of paediatric trials) timeframe.

If the national and global end dates coincide in a concerned Member State, the form shall be submitted only once to the National Competent Authority of this Member State with both sections D1.1. and D2.1 complete.

[4] Cf. Section 4.2. of the detailed guidance CT-1.

[5] Section 4.3. of the detailed guidance CT-1.